DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 29, 2014

Edwards Lifesciences
% Ms. Susan Reynolds
Regulatory Affairs Principal Project Manager
One Edwards Way
Irvine, California 92614

Re: K142199
Trade/Device Name: Ascendra Balloon Aortic Valvuloplasty Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty Catheter
Regulatory Class: Class II
Product Code: OZT
Dated: August 8, 2014
Received: August 11, 2014

Dear Ms. Susan Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Ascendra Balloon Aortic Valvuloplasty Catheter

Indications for Use *(Describe)*
The Ascendra Balloon Aortic Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Submitter: Edwards Lifesciences, LLC
One Edwards Way
Irvine, CA 92614

Contact: Susan Reynolds, Phone: 949-756-4518, Fax: 949-809-5655

Prepared: August 8, 2014

Trade Name: Ascendra Balloon Aortic Valvuloplasty Catheter

Common Name: Balloon aortic valvuloplasty catheter

Classification: Balloon aortic valvuloplasty catheter, 21 CFR 870.1255, Product Code OZT

Predicate Device(s): Loma Vista Medical (BARD) TRUE Dilation Balloon Valvuloplasty Catheter (K121083)

NuMed Z-MED and Z-MED II™ Balloon Aortic Valvuloplasty Catheter (K122012)

Device Description:

The Edwards Ascendra Balloon Aortic Valvuloplasty Catheter is used for balloon aortic valvuloplasty. The device consists of a coaxial polyamide catheter with a distal inflatable polyamide balloon intended to dilate (perform valvuloplasty on) the stenotic aortic valve prior to implantation of a bioprosthesis. Two radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. At the proximal end of the catheter, there is a standard "Y" connector for balloon inflation and a guidewire lumen. An inflation device may be connected directly or indirectly (using the supplied extension tubing) to the balloon inflation luer port of the catheter. The balloon is inflated by injecting a diluted contrast medium solution through the luer port (marked "BALLOON") on the "Y" connector. The device is supplied sterile for single use only. The BAVC is provided in a 20 mm size and is compatible with a 0.035" guidewire and a 14F sheath.

Indications for Use:

The Ascendra Balloon Aortic Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Comparison to Predicate:

The BAVC is substantially equivalent to Loma Vista Medical (BARD) TRUE Dilation Catheter, 510(k) No.: K121083 and the NuMed Z-MED and Z-MED II™ Balloon Aortic

Valvuloplasty Catheter, 510(k) No.: K122012 in intended use, design, technology and performance. The BAVC differs from the predicate devices in length.

Summary of Non-Clinical Testing:

Non-clinical testing was completed to demonstrate that the Ascendra balloon aortic valvuloplasty catheter meets the established performance characteristics, and to verify that design requirements are satisfied. Testing included biocompatibility evaluation per ISO 10993-1, ethylene oxide sterilization validation, and package qualification. Device functional testing included surface/visual Inspection, dimensional inspection, radiopacity, balloon diameter, insertion force into sheath, balloon inflation/deflation time, balloon compliance, catheter kink test, balloon catheter retrieval force, balloon fatigue and burst, leakage test, bond testing. The conclusions drawn from the non-clinical tests demonstrated that the device is substantially equivalent to the predicate devices.

Summary of Clinical Data:

Clinical assessment for the Ascendra balloon aortic Valvuloplasty catheter consisted of a literature review, comparison to currently marketed devices and complaint analysis. The assessment concluded that the use of BAV to predilate the aortic valve prior to TAVR or as a bridge to percutaneous or surgical aortic valve replacement is feasible and safe. This analysis, in combination with the results of the clinical trials reviewed as part of PMA P110021 and P130009, provides reasonable assurance that the Ascendra balloon aortic Valvuloplasty catheter is safe and effective for its indicated use.

Conclusion:

The Edwards Catheter is substantially equivalent to the predicate devices, Loma Vista Medical (BARD) TRUE Dilation Catheter and the NuMed Z-MED and Z-MED II™ Balloon Aortic Valvuloplasty Catheter.